

Response  
Applicants: Nicola Ghelli et al.  
Serial No.: 09/921,012

Attorney Docket: DID1040US

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**REMARKS**

Claims 1 – 18 are pending in this application. Claims 19 – 21 have been canceled.

**Acknowledgement of Examiner Telephone Interview:**

Examiner Leslie R. Deak is thanked for the courtesy of a telephone interview on December 16, 2004 with Applicants' representative, Cecilia Jaisle. This Response incorporates the substance of that interview and a previously submitted proposed Response. It is Applicants' understanding that this Response will place this application in condition for allowance.

**Rejection under 35 U.S.C. 103:**

Claims 1 – 18 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Pat. No. 4,662,829 to Nehring ("Nehring") in view of U.S. Pat. No. 5,413,599 to Imachi, et al. ("Imachi"), further in view of U.S. Pat. No. 4,673,393 to Suzuki, et al. ("Suzuki"). Withdrawal of this rejection as unsupportable is respectfully requested in light of the following remarks.

The teachings of Nehring in view of Imachi, further in view of Suzuki, or of any one or any combination of these references in connection with any other references of record, do not support a sustainable finding of obviousness of the present claims. According to Imachi, FIGS. 1 – 2, the movable valve membrane 1 "is mounted on the disk-shaped valve seat 2, and the valve seat 2 and movable valve membrane 1 are fixed at the centers thereof by setting member 5." (Col. 2, lines 57 – 63) According to Imachi, FIGS. 3:

In the valve apparatus of the present embodiment, a funnel-shaped valve seat 8 having many slit-shaped fluid-passing through holes 9 extending in the radial direction and a movable valve membrane 7 having a funnel-like shape conforming to the shape of the valve seat

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and being composed of a flexible membrane are fixed at the centers thereof by setting member 10.

(Col. 3, lines 55 – 62) Imachi further states, in reference to the embodiment of FIGS. 3, “The movable valve membrane is fixed substantially at the center thereof to the valve seat.” (col. 4, lines 12- 13) The Imachi movable valve membrane is clearly free, not fixed, about its peripheral edge. Imachi does not meet the terms of claims 1, 7 and 13 that require a blood outlet valve including a flexible material having a peripheral edge affixed to the exterior surface. The Examiner cites Nehring for its supposed disclosure of a pump with a housing. Nehring contains no teaching that supplies the above-noted deficiencies of Imachi.

The Examiner acknowledges, “Imachi fails to disclose that his valve is attached to the housing at the periphery of the flexible membrane.” Suzuki describes a prior art catheter introducer (FIGS. 1-2) designed “to prevent a blood flow to the outside through the path of the main body of the introducer” (col. 1, lines 30-36). Suzuki describes the structure and purpose of the two valve bodies in the prior art catheter introducer.

The first valve body 5 is provided at the central portion thereof with a round opening 5A, and makes it possible to prevent a blood leak under conditions where the catheter 4 is inserted into the path of the main body 2. The second valve body 6 is provided at the central portion thereof with a slit 6A, and makes it possible to prevent a blood leak when the catheter 4 is not inserted through the path of the main body 2.

(Col. 1, lines 44-52.)

There is no motivation in Nehring, Imachi and/or Suzuki to combine these teachings, and the Examiner provides no such motivation. Further, the Imachi medical valve apparatus would be inoperative if the periphery edges of his flexible membrane (valve 1) were attached to the housing (duct 6), in the manner the Examiner suggests, and as required for the Suzuki prior art catheter introducer to

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be combined with the other references in a manner called for by the present claims. The blood pump of the present claims would be inoperative if the flexible material of the blood outlet valve did not have its peripheral edge affixed to the exterior surface.

In the Final Rejection, the Examiner states, "Sealing the valve at the periphery of the Imachi device does not seal or otherwise occlude flow through the radial openings of the [valve] ... disclosed by Imachi." During the above-referenced telephone interview, Applicants' representative pointed out to the Examiner that sealing the valve at the periphery of the Imachi valve would indeed seal and occlude flow through the radial openings 3, 3' of the Imachi valve. Applicants' representative referenced the disclosure of Imachi in the Abstract, "at the time of back flow, the flexible membrane is wide-spread to adhere to the valve seat and close the through holes whereby the passage of regurgitation is prevented." Improvement of regurgitation characteristics is an important objective of the Imachi valve: "A primary object of the present invention is to provide a medical valve apparatus characterized in that the ... regurgitation characteristics ... are improved." (Col. 1, lines 57-66) Imachi further emphasizes that when the flexible membrane 1 adheres to the valve seat 2 the through holes 3, 3' are closed to prevent fluid passage there through. "[A]t the time of back flow, the flexible membrane is wide-spread to adhere to the valve seat and close the through holes whereby the passage of the regurgitation is prevented." (Col. 2, lines 10-13) "At the time of back flow, as shown in FIG. 2B, the movable valve membrane 1 is spread flat and adheres to the surface of the valve seat 2 to close the fluid-passing through hole 3 and prevent blood from flowing backward toward the blood pump in the case of outlet side." (Col. 3, lines 17-22) Accordingly, sealing the valve at the periphery of the Imachi valve would indeed seal and occlude flow through the radial openings 3, 3' of the Imachi valve.

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The Court of Appeals for the Federal Circuit has been consistent in finding non-obviousness where a proposed combination would render either the invention or a prior art reference inoperable. "If references taken in combination would produce a 'seemingly inoperative device,' we have held that such references teach away from the combination and thus cannot serve as predicates for a prima facie case of obviousness." *McGinley v. Franklin Sports Inc.*, 60 USPQ2d 1001, 1010 (Fed. Cir.2001) (citations omitted). M.P.E.P. 2143.01 Suggestion or Motivation to Modify the References, at page 2100-131, The Proposed Modification Cannot Render the Prior Art Unsatisfactory for Its Intended Purpose, states, "If proposed modification would render the prior art invention being modified unsatisfactory for its intended purpose, then there is no suggestion or motivation to make the proposed modification." Therefore, the Examiner's proposed combination does not suggest or render obvious a pump having the features of the claimed invention.

Claims 2 – 6, 8 – 12 and 14 – 18 provide other patentable features that further distinguish over any and all of the references of record, taken separately or together in any combination.

Nehring in view of Imachi, further in view of Suzuki, or any one or any combination of these references or taken with any of the other references of record in any combination, do not provide a sustainable finding of obviousness of the present claims. Withdrawal of this rejection is seen to be in order and is solicited.

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CONCLUSION

In view of Applicants' remarks, claims 1 – 18 are in condition to be allowed. Should the Examiner consider that any other minor matters remain prior to the issuance of a Notice of Allowance, the Examiner is requested to telephone the undersigned to reach prompt resolution thereof.

If any additional fees are due in connection with the filing of this paper, please charge the fees to our Deposit Account No. 16-2312. If a fee is required for an extension of time under 37 C.F.R. § 1.136 not accounted for above, such an extension is requested and the fee should also be charged to our deposit account.

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Respectfully submitted,

Date: 12/20/04By: 

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